ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA, *ex rel.* [UNDER SEAL], Plaintiff, v. [UNDER SEAL], Defendant.	No. 1 10-CV-1614 COMPLAINT JURY TRIAL DEMANDED FILED IN CAMERA AND UNDER SEAL

[FILED IN CAMERA AND UNDER SEAL]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA, *ex rel.* CHESTER SALDIVAR, Plaintiff, v. FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, Defendant.	No. COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT JURY TRIAL DEMANDED Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

TABLE OF CONTENTS

Plaintiff-relator Chester Saldivar, through his counsel and on behalf of the United States of America, in this Complaint against defendant Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America ("FMCNA" or "Fresenius"), alleges based upon personal knowledge and relevant documents, as follows:

I. INTRODUCTION

1. This action is brought by relator Chester Saldivar on behalf of the United States of America to recover treble damages and civil penalties under the False Claims Act, as amended, 31 U.S.C. § 3729, *et seq.* ("the FCA" or "the Act"), arising from fraud upon the United States Government in connection with defendant's improper, fraudulent, and unlawful claims for reimbursement submitted by it to Medicare, CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefits Program.

2. As a recognized dialysis clinic provider, FMCNA is generally entitled to some reimbursement by federal health care programs for acquisition costs associated with treating the more than 100,000 end-stage renal disease ("ESRD") patients undergoing dialysis at its chain of clinics. FMCNA is a wholly-owned subsidiary of German-based Fresenius Medical Care AG & Co. KGaA, the world's largest provider of medical products and services for persons undergoing dialysis

treatment. FMCNA reported revenue of over $7 billion in 2008 and is America's largest dialysis services provider. Unfortunately, some of this massive revenue was obtained from the United States Government by fraud.

3. In addition to composite payment from Medicare for the dialysis treatment regime patients undergo at these clinics, FMCNA is entitled to bill Medicare separately for reimbursement of certain injectable medications it purchases and separately administers to dialysis patients. Medicare is a reimbursement system. Under it, health care providers are reimbursed for a portion of the costs that they incur treating Medicare beneficiaries. Thus, a provider such as FMCNA cannot bill Medicare for drug product it received for free. This is also true of the other federal health care programs.

4. In this matter, though entitled to submit claims to Medicare for reimbursement relative to brand-name injectable drugs Zemplar (paricalcitol) and Epogen (epoetin alfa), both of which are administered to dialysis patients at its clinics across the U.S., FMCNA has for many years sought and received many millions of Medicare reimbursement dollars for payment of drug product that FMCNA itself got for free. Following receipt from the Government of these ill-gotten gains, FMCNA never disclosed and has continued to conceal from Medicare these overpayments.

5. FMCNA's fraudulent scheme to bill Medicare and other federal health care programs for reimbursement of costs never incurred has resulted in significant damage to the federal treasury. Injectable drugs administered to ESRD patients cost billions of dollars annually, most of which is paid by Medicare. Medicare reimbursement for both Zemplar and Epogen is in the hundreds of millions of dollars annually, with fraudulently obtained reimbursement to the defendant accounting for a significant portion of those totals.

6. Because the law prohibits providers such as the defendant from billing Medicare and other federal programs for drug the providers received for free, *qui tam* plaintiff Mr. Saldivar brings this action to recover damages and civil penalties arising from FMCNA's unlawful billing, receipt, and retention of reimbursement monies obtained in plain violation of the False Claims Act.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), the latter of which specifically confers jurisdiction on this Court for actions, such as this, brought pursuant to 31 U.S.C. § 3730(b) for violations of Section 3729. Within the meaning of 31 U.S.C. § 3730(e)(4)(A), there has been no public disclosure of the "allegations or transactions" in this Complaint. In the alternative, if the Court were

to find a public disclosure, relator Saldivar is an original source under 31 U.S.C. § 3730(e)(4)(B), with independent knowledge that materially adds to any public disclosure and who provided his information to the Government prior to filing this action.

8. This Court has personal jurisdiction over the defendant and is a proper venue pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a). The defendant can be found in, resides, transacts, or has transacted business in the Northern District of Georgia.

9. At all times relevant to this Complaint, defendant has regularly conducted substantial business within the Northern District of Georgia and has generated significant revenue within the District.

III. PARTIES

10. Plaintiff-relator Chester Saldivar is a resident of the state of California. Mr. Saldivar was employed by Fresenius in its Los Angeles region from March 31, 2007, until his termination on or about December 18, 2009. During that time, Mr. Saldivar was promoted to Chief Equipment Technician covering both the defendant's East Los Angeles and Mid Wilshire dialysis clinics.

11. Defendant FMCNA is a wholly-owned subsidiary of Fresenius Medical Care AG & Co. KGaA, which is located in Bad Homburg, Germany.

Fresenius Medical Care AG & Co. KGaA is a registered partnership. FMCNA is headquartered in Waltham, Massachusetts. According to its websites,[1] FMCNA employs over 40,000 employees and treats nearly 130,000 patients at its roughly 2,000 outpatient dialysis clinics in the United States, including several in this District.

IV. BACKGROUND

A. End-Stage Renal Disease (ESRD) and Dialysis

12. Chronic kidney disease (also termed chronic renal disease) refers to the progressive loss of a person's kidney function. It is often detected among those with high blood pressure or diabetes, and it can lead to cardiovascular disease or anemia. Anemia is a decrease in the normal number of red-blood cells and/or hemoglobin in a person's blood.

13. A person with chronic kidney disease is typically classified into one of five stages of severity, with stage 5 being the most dire. At stage 5, a patient is considered to have end-stage renal disease, also called chronic kidney failure. The treatment options available to persons suffering ESRD are usually limited to dialysis treatment or a kidney transplant.

[1] *See* http://www.fresenius.se and http://www.FMCNA.com/, last accessed May 22, 2010.

14. Several hundred thousand Americans regularly undergo a regimen of dialysis treatments to combat ESRD. Dialysis (from the Greek "dialusis," meaning dissolution) refers now to a treatment regimen aimed at artificially replacing some of the functions performed by a healthy kidney. Dialysis, however, is an imperfect substitute for healthy kidney function. Healthy kidneys both help excrete end products from the body and are part of the endocrine system; they produce erythropoietin and calcitriol, which affect red-blood cell production and bone formation, respectively. Dialysis helps with waste and fluid removal, but does not substitute for the kidney's endocrine functions.

15. Two types of dialysis are common – hemodialysis and peritoneal. Both aim to reduce waste and remove excess water from the blood.

16. Hemodialysis does this by circulating blood outside the body through a dialyzer. Blood flows out of the body, and a dialysate solution flows in. The ingredients found in the dialysate solution are calibrated to the needs of the individual patient. In the U.S., this type of dialysis is typically performed at one of several thousand free-standing dialysis clinics, the largest chain of them owned by the defendant.

17. By contrast, less common peritoneal dialysis is performed at a patient's home, and involves use of a sterile glucose solution running through a

tube in the peritoneal (abdominal) cavity surrounding the intestine that over time absorbs waste products and is then discarded.

18. Roughly 90 percent of all dialysis patients undergo hemodialysis at a dialysis clinic three times per week. For these patients, in addition to the dialyzer treatment described above, separately injectable medications including Epogen (a brand name for a synthetic form of erythropoietin) and Vitamin D analogs such as Zemplar (the brand name for paricalcitol, the dominant analog product) are usually administered.

19. In brief, Epogen, a hormone approved by the FDA for ESRD treatment since 1989, lessens the effects of anemia by increasing red blood cell levels. Zemplar, an analog of calcitriol (the active form of vitamin D), treats secondary hyperparathyroidism by attempting to halt the excessive secretion of parathyroid hormones triggered itself by low blood calcium levels.

B. Medicare Reimbursement for Treatment of ESRD

20. Modern dialysis to treat ESRD was beyond the financial reach of most Americans until a 1972 amendment to the Social Security Act extended Medicare dialysis coverage to nearly all ESRD patients regardless of age or other factors. Medicare has since been the primary payor for more than 80% of the roughly 500,000 ESRD patients in the United States.

21. According to Congress[2] and the U.S. Renal Data System,[3] ESRD expenditures by Medicare exceeded $5 billion annually by 1991, and now exceed $20 billion annually.

22. Since 1983 Medicare has reimbursed providers a composite rate for outpatient maintenance dialysis services, which most patients receive three times per week at clinics such as those owned by defendant. This composite rate reimburses provider acquisition costs associated with a single dialysis treatment, including nursing and other clinical services, social services, supplies, equipment, and some laboratory tests and drugs. 42 U.S.C. § 1395rr. Certain injectable drugs, however, have remained outside the composite payment, including both Zemplar and Epogen, and providers bill separately for reimbursement of their acquisition costs. *See* Medicare Claims Processing Manual, "Separately Billable ESRD Items and Services," Chapter 8 § 60 ("An item or service is separately billable if its cost was specifically excluded from cost data used to calculate the composite rate.").

23. The Medicare ESRD program is administered through the Centers for Medicare and Medicaid Services ("CMS"). CMS-contracted fiscal intermediaries

---

[2] Congressional Kidney Caucus, at http://www.house.gov/mcdermott/kidneycaucus/numbers.html, last accessed April 19, 2010.

[3] U.S. Renal Data System, "Precis," http://usrds.org/2007/pdf/00a_precis.07.pdf., last accessed April 19, 2010.

process and pay Medicare Part B reimbursement claims to providers such as FMCNA for these separately billed injectable drugs. 42 C.F.R. § 413.174(f).

24. Congress, in the 2003 Medicare Prescription Drug Improvement and Modernization Act ("MMA"), mandated that the Office of Inspector General study the difference between the reimbursement costs associated with the drugs and biologicals billed separately to CMS, and the "acquisition costs for the ESRD facilities that bill for these drugs."[4] Even where a provider bills legitimately for drug actually purchased, CMS reimbursements exceed by significant margins the actual acquisition costs to providers for injectable drugs such as Zemplar and Epogen. Since 2003, Congress has made efforts to reduce "Medicare's pre-2005 generous payments for separately billable ESRD drugs;" particularly generous to "[l]arge chains [which] tend to receive volume discounts on ESRD drugs."[5]

25. The fixed nature of composite payments from Medicare provides a perverse incentive for providers to overbill for the variable-cost items, such as

[4] *See* "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs," Department of Health and Human Services – Office of Inspector General, May 2004 (Appendix A).

[5] *See* Report to the Chairman, Committee on Ways and Means, House of Representatives, United States Government General Accountability Office, "End Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility," November 2006, at 1-2 ("GAO 2006 Report").

injectable drugs, that are not bundled into the composite payment. According to CMS, separately billable services currently comprise roughly 40% of total spending for outpatient dialysis. The more doses of injectable drugs that are billed to Medicare, the more profit a provider can make. CMS has noted recently that one "objective" of a current plan to include all injectable drugs within the composite payment system is "eliminating incentives" to make improper use of "profitable separately billable drugs."[6]

26. From 1998-2005, payment for certain ESRD drugs covered under Medicare Part B was determined based upon so-called Average Wholesale Price calculations until it was discovered that this price was itself subject to variation and abuse.[7] Epogen, on the other hand, was billed at the rate of $10 per 1,000 units during that time period. In the 2003 MMA, with abuses in mind, Congress "mandated that in 2005 Medicare pay for separately billable ESRD drugs based upon their acquisition costs, as determined by the HHS Office of the Inspector General (OIG)."[8] And beginning in 2006 and continuing through the present date, Medicare has reimbursed for Zemplar and Epogen in the ESRD setting at the rate

[6] Federal Register, Sept. 29, 2009 Proposed Rules CMS, 42 C.F.R. Parts 410, 413, 414.

[7] *See* GAO 2006 Report, at 11.

[8] *Id.*

of Average Sales Price (as determined by CMS on the basis of manufacturer submittals) + 6%.

27. Typically, a provider such as FMCNA will submit one reimbursement claim bill per month for a given patient, including the charges for several dialysis treatments, any separately billable laboratory services, and separately billable drugs such as Zemplar or Epogen. Since 2005, Zemplar and Epogen have combined to account for over 80% of the total CMS reimbursement for billable ESRD drugs.[9]

28. Additionally, as an independent renal dialysis facility, FMCNA is required to annually submit Medicare cost reports (CMS-Form-265-94) which disclose cost data and include an express certification of compliance with all applicable laws as a condition of coverage by Medicare. 42 C.F.R. § 413.20.

29. Most recently, since passage of the Medicare Improvements for Patients and Providers Act of 2008, providers have been made aware that a prospective composite payment to include injectable drugs will soon be implemented, and that new system is now slated to begin an initial phase-in in 2011. Providers have been aware that a narrow window of time exists within

[9] *See* GAO 2006 Report, at 10.

which to maximize Medicare reimbursement for injectable drugs – whether lawfully or unlawfully.

1. Medicare reimbursement for the acquisition costs of Zemplar

30. The vast majority of defendant's ESRD patients, like ESRD patients generally, receive an injectable administration of the Vitamin D analog paricalcitol on a regular basis. FMCNA provides its patients with the brand name Zemplar, the dominant brand in the market.

31. Zemplar is a separately billed injectable drug, subject to Medicare reimbursement of acquisition costs to dialysis providers such as the defendant. Since 2003, Zemplar injections are billed for Medicare Part B ESRD reimbursement by providers such as FMCNA in 1 mcg (microgram) increments with the CPT/HCPCS Code J2501 (paricalcitol). A less common J2500 code is used for 5 mcg vials of Zemplar.

32. Zemplar is significantly more expensive than its competitor products, and reimbursement for it creates more profit for dialysis providers than use of a less expensive alternative drug. Medicare-allowable payments for Zemplar were in excess of $300 million in 2007.

33. FMCNA purchases Zemplar mostly in 2 mcg vials. FMCNA, like other recognized dialysis providers, is entitled to reimbursement from the Medicare

program, and other federal health care programs, for Zemplar administered to patients where FMCNA itself paid for the quantum of drug administered. *See* Medicare Claims Processing Manual, "Separately Billable ESRD Items and Services," Chapter 8 § 60 ("An item or service is separately billable if its *cost* was specifically excluded from cost data used to calculate the composite rate.") (emphasis added). Free drug provided to FMCNA, whether in the form of overfill or otherwise, may not be billed for reimbursement.

2. Medicare reimbursement for the acquisition costs of Epogen

34. Epogen, a brand of epoetin alfa, is administered by FMCNA to nearly all its ESRD patients, just as ESRD patients generally receive it, to treat anemia associated with renal disease. For facilities like those operated by the defendant, a pre-established dosing algorithm allows a nurse to adjust Epogen dosage to maintain optimum hematocrit (red blood cell) levels in the body.

35. Like Zemplar, Epogen is subject to reimbursement by the Medicare Part B ESRD program, and at times here pertinent it was billed in increments of 1,000 units (for ESRD patients on dialysis) with CPT/HCPCS Code J0886. A 100-unit Code Q4081 was added to the Coding catalogue in 2007. Medicare allowable payments for Epogen were in excess of $1.8 billion in 2007.

36. FMCNA, like other recognized dialysis providers, is entitled to reimbursement from the Medicare program, and other federal health care programs, for Epogen administered to patients where FMCNA itself paid for the quantum of drug administered. *See* Medicare Claims Processing Manual, "Separately Billable ESRD Items and Services," Chapter 8 § 60 ("An item or service is separately billable if its *cost* was specifically excluded from cost data used to calculate the composite rate.") (emphasis added). Free drug provided to FMCNA, whether in the form of so-called overfill or otherwise, may not be billed separately for reimbursement.

3. Drug overfill is not purchased and is not separately reimbursed by Medicare

37. As a marketing incentive and kickback, manufacturers of certain drugs, including Amgen (Epogen) and Abbott (Zemplar), often include volumes of drug in vials that far exceed the nominal volume of those vials and far exceed what might be required to ensure that the nominal volume can be pulled by practitioners into syringes.[10] That volume of overfill does not represent any additional cost to a provider. A provider might decide to administer overfill dosages (where not otherwise prohibited, *e.g.*, in rules issued by the Centers for Disease Control and

[10] *See* 21 C.F.R. § 201.51(g); USP Reference Standards, United States Pharmacopeia, XXXI, Gen. Ch. <1151> "Injections" (2008).

adopted by CMS), but it must avoid overpayment by Medicare to it by reducing the amount sought for reimbursement to reflect only actual costs incurred relative to vials actually used from inventory, and/or disclosing the overpayment to Medicare when it is learned of after the fact.

38. Where a provider such as FMCNA receives overpayment from Medicare as a result of improper "reimbursement" for unpurchased overfill volumes, that provider must notify Medicare, in its annual cost reports or otherwise, of the overpayment. It is unlawful to conceal such overpayments from Medicare.

39. Federal law recognizes that dialysis providers should receive reimbursement for an entire vial of a drug even when only a portion of the vial is appropriate to administer to a given patient. For that reason, Medicare will reimburse for the full amount of a purchased drug vial even if some portion of it has to be "wasted" because it exceeds the dosage appropriate for a given patient.

40. As the Medicare Claims Processing Manual makes plain,[11] where a "provider must discard the remainder of a single use vial or other single-use package after administering a dose/quantity of the drug ... to a Medicare patient,

[11] Medicare Claims Processing Manual, Chapter 17 "Discarded Drugs and Biologicals," § 40 (emphasis added).

[Medicare] provides payment for the amount of drug [ ] discarded along with the amount administered, *up to the amount of the drug or biological as indicated on the vial or package label*." When smaller volume vials are available for purchase, however, a provider will not get reimbursed for the waste associated with the remainder of a large volume vial that was purchased.

41. For example, if a 2 mcg vial of Zemplar is opened for administration and only 1.5 mcg is provided to the patient, the provider may indicate on its reimbursement bill to Medicare (handled by a fiscal intermediary) that the balance of .5 mcg was discarded (or "wasted"). What a provider may not do is either (a) administer the .5 mcg remainder and the overfill from the vial and bill for reimbursement from Medicare as if that .5 mcg plus overfill, or the overfill alone, were taken from an additional, purchased vial, or (b) state falsely to Medicare that the balance was discarded, while separately billing for the administration of it.

42. Where a provider has given multiple doses of a drug from a single vial, [12] or from the overfill compiled from otherwise billed single vials, and where

[12] Critically, at least since October 2008, the re-entry of single-use vials in the ESRD context has been strictly prohibited by CMS. *See* 42 C.F.R. §§ 494.30(a)(1)(i) and (b)(2); http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5732a3.htm, last accessed May 24, 2010. Defendant's violation of this plain CMS mandate provides a separate, independent basis for liability under the False Claims Act. Every claim for

it has billed Medicare as if each dosage was in fact from an additional purchased vial, it is incumbent upon the provider to notify Medicare voluntarily of the overpayment and to make provision for prompt repayment.[13]

Reimbursement Under Other Federal Health Care Programs

43. In addition to Medicare, the federal government provides reimbursement, in whole or part, for approved injectable drugs such as Zemplar and Epogen under several other federal health care programs, including, but not limited to, CHAMPUS/TRICARE, CHAMPVA, and the Federal Employees Health Benefit Program.

44. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee

---

reimbursement based on re-entries into single-use vials is false because it is not properly reimbursable.

[13] Overfill, as captured, administered, and billed by Fresenius, additionally runs afoul of federal law regulating free drug product. Under the Prescription Drug Marketing Act, a provider may not make a claim to Medicare for reimbursement of costs associated with the administration of free drug, given that the provider does not pay any cost for its procurement and its purchase and sale are prohibited. *See* 21 U.S.C. § 353(c) & (d). In many circumstances, such practices also run afoul of the Anti-Kickback Statute. 42 U.S.C. § 1320a-7b.

Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

45. As with Medicare, providers such as the defendant are not eligible for payment under these programs for the administration of injectable drugs where no costs were actually incurred in their acquisition.

V. ALLEGATIONS

A. FMCNA's Fraudulent Overfill Scheme

46. As Mr. Saldivar directly and independently learned during his employment as an Equipment Technician at FMCNA clinics in Southern California from 2007 through 2009, the defendant has for many years required its clinics to collect, track, administer, and bill for overfill volumes of both Zemplar and Epogen. Of the total monthly doses administered at each clinic, the defendant requires that 10-13% of Epogen administered doses, and 22-30% of Zemplar administered doses, be taken from the overfill volumes captured from purchased vials of the respective drugs.

47. Because FMCNA did not incur any costs in the purchase of these overfill volumes, it has profited handsomely at taxpayer expense by unlawfully submitting to CMS claims for reimbursement for acquired drug costs never

incurred for its goal of 10-13% of its Epogen treatment volumes, and 22-30% of its Zemplar treatment volumes.

48. Drugs such as Heparin, reimbursed by Medicare as part of the prospective composite payment discussed above, were not separately tracked by FMCNA for overfill usage – only those drugs that could be separately, and fraudulently, billed to Medicare for separate, purported "reimbursement."

49. Mr. Saldivar learned of the defendant's emphasis on overfill usage requirements immediately upon beginning his work at FMCNA. Mr. Saldivar began work as an Equipment Technician at Fresenius clinics in March of 2007. He was employed in FMCNA's West Business Unit in the Los Angeles South/Nevada Region which includes within it the Los Angeles East Area. Within that Area, Mr. Saldivar was employed at both the East Los Angeles and Mid Wilshire clinics (Nos. 3820 and 2869, respectively). The East L.A. clinic opened for patients at the end of 2006.

50. On a regular basis, from corporate headquarters down to area managers and then to clinical managers, both monthly and quarterly reports were sent, reminding of the company's overfill percentage goals, and listing clinic performance nationwide in terms of overfill percentage for Epogen and Zemplar administered to patients. Because he was charged with accounting for Zemplar

vials, and later Epogen vials, Mr. Saldivar was shown these reports each month and quarter by his clinical managers at the time. These managers were Caesar Del Rosario, followed by his replacement Aurora Alegre, at the East L.A. Clinic (3820), and Flerida Jose at the Mid Wilshire Clinic (2869).

51. As part of the effort to incentivize its workforce to collect and administer overfill doses diligently, FMCNA made bonus payments to employees working at those clinics with the highest overfill percentages, as part of overall performance Diamond Awards. Mr. Saldivar's East L.A. clinic received this award in early 2009 in recognition of its #1 ranking for more than one quarter of 2008, including recognition of its high overfill percentages for both Zemplar and Epogen. Area Manager Catherine McLaughlin called to personally thank Mr. Saldivar for the clinic's high overfill administration percentage for Zemplar, since Mr. Saldivar was the person responsible for submitting the monthly Zemplar overfill reports (discussed further below).

52. Clinical Managers Del Rosario, Alegre, and Jose regularly reminded Mr. Saldivar during one-on-one conversations and in management meetings of these overfill requirements, and they were regularly discussed among management (and Mr. Saldivar) when monthly and quarterly performance reports were circulated. Later, in September of 2009, when Mr. Saldivar began Epogen

inventory work, clinic manager Alegre discussed the need to keep overfill percentages high for Epogen, as they had been kept for Zemplar.

53. When Zemplar overfill administration percentages fell below the expected minimum of 22%, Mr. Saldivar received more than one call from Area Manager McLaughlin expressing her concern that clinic personnel were not capturing and administering enough Zemplar overfill. It was Mr. Saldivar's responsibility to inform his clinical manager and nurses that more overfill needed to be collected and used.

54. On both Zemplar and Epogen inventory forms (monthly and daily forms), total administered doses were routinely recorded and calculated to clarify the average dose both *with* and *without* use of overfill, and the overfill percentage of administered doses for the month was highlighted (as discussed further below). This allowed FMCNA to determine on an ongoing basis just how much overpayment it could capture from the Medicare system, and other federal programs, by its indulgent use and billing for overfill administrations of Zemplar and Epogen.

55. By virtue of the capture and dosing with overfill volumes, the total administered dosages at a given clinic never equaled the total available drug amount from the clinic inventory. Far more dosages were always administered

than the drug labeled volumes in inventory could provide. Instead, a high percentage of total doses both daily and monthly as to both Zemplar and Epogen were derived exclusively from unpurchased drug overfill – overfill subsequently billed primarily to Medicare.

56. Because FMCNA's reimbursement bills and cost reports submitted to the Government did not set forth the total number of administered dosages as compared to the total number of vials purchased, the Government has not been able to detect the unlawful, and successful, efforts to obtain funds for unpurchased, no-cost overfill amounts. FMCNA's mechanism of fraud has also prevented the Government from learning the extent of overfill being "reimbursed" by it, far in excess of USP-recognized volumes.

57. In September 2009 Mr. Saldivar was asked by manager Alegre to include among his job responsibilities an accounting of Epogen vial inventory as part of the monthly usage inventory analysis which he had already been performing for other drugs, including Zemplar. Mr. Saldivar performed this Epogen inventory work at the 3820 clinic, while a subordinate technician did the accounting at the 2869 clinic.

58. Mr. Saldivar immediately noted discrepancies in the inventory numbers for Epogen (the vial count provided to him vs. the visual vial count he

observed), and brought them to the attention of the head nurse, Jin Xiashin, and his clinic manager Alegre in September, October, and November of 2009. Because he was required to sign and attest personally to the accuracy of the Epogen inventory count, he was concerned about the provision of false information.

59. After his complaints to management about the inaccurate reporting of Epogen inventories, Mr. Saldivar was suspended for an "investigatory period" beginning November 30, 2009, and he was subsequently terminated without explanation on December 18, 2009.

B. FMCNA's Fraudulent Scheme to Capture, Administer, and Seek Reimbursement for Zemplar Overfill

60. As noted above, a majority of dialysis patients treated at FMCNA clinics receive Zemplar, the most lucrative Vitamin D analog a dialysis clinic can provide. As a means of generating additional income from the administration of Zemplar, FMCNA incorporated the collection, administration, and billing of Zemplar overfill into its business plans, and encouraged its clinics to maximize the amount of overfill to be billed to Government health plans, primarily Medicare.

61. FMCNA submitted false claims to Medicare, and other federal programs, for reimbursement of Zemplar overfill by falsely claiming that such overfill amounts came from additional purchased vials, when in fact FMCNA paid no cost for their acquisition.

62. FMCNA kept meticulous track of the economic gain it would receive from the billing of Zemplar overfill to Medicare and other federal programs. In its Vitamin D Supplements Inventory Usage Analysis spreadsheet documents, generated every month by the defendant clinics, FMCNA took care to document, *inter alia*, (i) the total physical inventory of purchased Zemplar vials at the beginning and ending of the month; (ii) the total number of Zemplar doses administered for the month; (iii) the total units (mcgs) of Zemplar administered for the month; as well as (iv) average dosage administered from purchased vials as compared to total mcgs used, and (v) the percentage of overfill used that month as part of the monthly total of administered doses. Mr. Saldivar sent these documents each month to Louise Clark at the company's Tempe office, where he was told by his clinical manager Alegre the documents were used as the basis upon which the company billed for reimbursement and for that reason were important documents.

63. Mr. Saldivar was given primary responsibility for Zemplar usage analysis tracking and reporting in January 2008. It was his responsibility, at both the 2869 and 3820 clinics, to prepare the Usage Analysis documents for Zemplar by counting the inventory physically and retrieving the information on "total administered doses" from the patient information database, called the "Proton" system, which supplied him the number automatically. Once those items were put

into the Usage Analysis spreadsheet, the algorithm in the document produced the average dose, average mcg used from inventory, and overfill percentages. The clinic manager was responsible for approving each month's Usage Analysis report for Zemplar.

64. In 2007 and until December of 2008, Mr. Saldivar created these monthly Zemplar reports and observed the high percentages of Zemplar overfill accounting for up to nearly 30% of the total doses administered at clinics.

65. One example (among several in Mr. Saldivar's possession) is illustrative of the information tracked and disclosed in these Usage documents, and evidence of the improper billing for overfill. In November 2008, at the 3820 Clinic, the Zemplar Usage Analysis document was prepared by Mr. Saldivar and approved by the clinic manager Alegre. The beginning inventory of 2 mcg vials of Zemplar is listed as 499, with 750 additional 2 mcg vials purchased on November 3. The balance remaining at the end of November is listed as 801, with 448 vials listed for November's "Usage."

66. The "Usage" in micrograms for the month of November is listed as 896 – exactly double the 448 2-mcg vials that were used to treat patients. The number of doses administered, however, exceeds the 896 mcgs, as it did every

month that was tracked by Mr. Saldivar. This is because unpurchased overfill supplies a significant volume of the total administered doses.

67. In order to track the amount of overfill being utilized for billing purposes, the November 2008 Usage document also lists the "Total Doses Administered" - 1153 mcgs for November. The "Total Doses Administered" was reported on every Usage document prepared by Mr. Saldivar until December of 2008.

68. Mr. Saldivar, each month, retrieved this number from the patient database system, a number that reflected the total monthly patient data for all persons who received Zemplar dosages at the clinic, and the mcgs used to treat them. The difference between the 896 mcgs used in November from the purchased vials, and the 1153 total mcgs reportedly used on patients, constitutes the overfill administered to them. The Usage document itself spells out the overfill usage even more straightforwardly.

69. The Usage spreadsheet, after entering the aforementioned information, automatically generates the average dose, the mcg amount used from the purchased inventory of 2 mcg vials, and the percentage of overfill. For November, the average dose was 3.53 mcgs, with an average of 2.74 mcgs used from inventory, and an overall "Overfill" percentage of 28.83% for the month. In

other words, in addition to the total 896 mcgs drawn and administered from purchased vials, another 257 mcgs (or 128 vials worth) of free overfill drug were also administered (the difference between the 1153 "Total Doses" and the 896 "Mcgs Used") and subsequently billed as if they represented an additional 128 purchased vials. In fact, they represented 128 vials worth of free drug. Similar numbers and the identical tracking of overfill can be found on the balance of Usage spreadsheets Mr. Saldivar prepared and has in his possession.

70. At the end of 2008, Mr. Saldivar and others received an email from Area Manager McLaughlin, originally sent from corporate headquarters, stating that beginning in December the overfill amounts would no longer be recorded in the inventory usage forms for Zemplar. From December 2008 forward, the "Total Administered Doses" as well as the corresponding Avg. Dose, mcgs used, and "Overfill" information is simply redacted. Throughout 2009, Mr. Saldivar's Zemplar Usage spreadsheets were uniformly redacted (automatically via the computer program) to conceal the Zemplar overfill and administered doses information, though Epogen overfill continued to be tracked in inventory documents. Upon information and belief, the use and billing of overfill, despite the 2008 CMS rule change on multiple extractions from single-use vials, continued at FMCNA and continues still.

71. This accounting system has allowed FMCNA to compare Zemplar overfill percentage performance month-to-month, and across all of its clinics. Since Medicare "reimbursement" for the overfill amounts constituted pure profit for the defendant, which paid no acquisition costs to obtain those *de facto* drug sample volumes, every incentive existed to maximize the overfill numbers. The Zemplar overfill goal of 22-30% was regularly achieved – at taxpayer expense.

C. FMCNA's Fraudulent Scheme to Capture, Administer, and Seek Reimbursement for Epogen Overfill

72. Virtually all patients who receive dialysis treatment at the defendant's clinics receive as part of their treatment injectable dosages of Epogen to address the effects of anemia.

73. At FMCNA clinics, Monthly Erythropoietin (Epo) Analysis documents track the Monthly Usage of vials (EPO 20,000/1ml), the Actual Units Administered, Avg. Dose per Treatment, Total Usage per Treatment, and the overfill amounts administered. This Monthly Analysis documents the details of the defendant's utilization of overfill for billing purposes, just as the Inventory-Usage document similarly documents the overfill metrics for Zemplar.

74. By way of example (and among several documents in Mr. Saldivar's possession), the 3820 Clinic's Monthly Epo Analysis document for the month of October 2008 states that 34 1-ML vials (20,000 units) of Epogen were "used" that

month for a total of 680,000 units and an average treatment dose of 4,146.34 units. This, at a total cost of $7,997.55, or $48.77 "Cost per EPO" Treatment.

75. As with Zemplar, however, the total "Actual Units Administered" (supplied by the patient Proton database) for the month of October exceeded 680,000 units (or 34 MLs worth of vials) because overfill was captured and administered as well. The "Actual Units Administered" is listed as 762,000, for an "Avg. Dose per Epo Treatment" of 4,649.39 units, as compared to the 4,146.34 units per treatment actually taken from purchased vials of Epogen. The "Utilization Efficiency" (FMCNA's Epogen euphemism for overfill) is listed at 12.1% - exactly the difference between the 680,000 units administered to patients from the 34 purchased vials of Epogen, and the total of 762,000 units *actually administered* to patients that month. That 12.1% constitutes the 82,500 units of no-cost, unpurchased Epogen drug overfill that were captured, administered, and later billed (primarily to Medicare) that month.

76. The October Analysis proceeds to list the "Billable EPO" treatment at 164. FMCNA subsequently billed payors, primarily Medicare, for a total of 762,500 units administered for 164 treatments, even though it only incurred acquisition costs for 680,000 of those units.

77. FMCNA's Monthly Epo Analysis Instructions form makes clear that the Monthly Epo Analysis document must be sent to the Tempe Financial Center Office (so too with Zemplar), and that the patient dose information taken from the Proton system (which includes utilization of overfill doses) also be sent in "summary" form along with the Analysis. Combined, this information provided all that was necessary from FMCNA clinics to allow the defendant to bill Medicare, and other federal programs, falsely for "reimbursement" of overfill volume for which it never incurred acquisition costs.

78. Until September of 2009, only the clinic manager, or secretary under the direction of the manager, could access or prepare these Epogen documents. Mr. Saldivar was assigned to begin working on them in September of that year. By that time, however, the form had been changed to prevent obvious detection of the overfill tracking.

79. Daily Reconciliation sheets for Epogen at Fresenius clinics also track the overfill percentages and were regularly reviewed by Mr. Saldivar in 2009. Mr. Saldivar has a number of these Reconciliation sheets in his possession, each of them showcasing the high volumes of overfill administered and subsequently billed.

80. As with Zemplar, this accounting system allowed FMCNA to compare overfill percentage performance month-to-month, and across all of its clinics. Since federal health care program "reimbursement" for the overfill amounts constituted pure profit for the defendant, which paid no acquisition costs to obtain those volumes, every incentive existed to maximize the overfill numbers. Just as with Zemplar, the Epogen overfill goal of 10-13% was regularly achieved – also at taxpayer expense.

VI. CONCLUSION

81. The Medicare program generously, and at great cost, provides reimbursement to dialysis providers that incur actual costs in acquiring injectable drugs to treat ESRD patients, but only for drug actually purchased. Eager to profit at taxpayer expense, the defendant has taken millions of dollars unlawfully from federal health care programs as purported "reimbursement" money for costs never borne by it. Indeed, as alleged above, it has persisted in its policy of capturing overfill and billing for it even after CMS regulations made plain that multiple entries into single-use vials were prohibited. Because the reimbursement principles of Medicare, and the other federal health care programs, do not permit such fraudulent claims and concealment by dialysis providers, relator, on behalf of the United States, seeks in this action to recover FMCNA's ill-gotten gains.

COUNT I

FALSE CLAIMS ACT

31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B)

82. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 81 of this Complaint.

83. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

84. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, and made, used and caused to be made and used false records and statements material to false claims. Each claim for reimbursement of acquisition costs for administered doses of Zemplar taken from the overfill of purchased vials which themselves were the subject of separate reimbursement claims is a false claim. The defendant did not pay any drug costs for the Zemplar overfill doses, and it was not entitled to receive any additional reimbursement from Medicare or other federal health care programs for such doses. By submitting false claims seeking reimbursement for vials of Zemplar that were never purchased by it, defendant violated 31 U.S.C. § 3729(a)(1)(A) and

(a)(1)(B) and caused the federal government to pay it funds to which it was not entitled.

85. The Government, unaware of the falsity of the records, statements, and claims made or caused to be made by the defendant, has paid and continues to pay the defendant for reimbursement of purported drug costs never actually incurred by defendant and to which it is not entitled.

86. By reason of the defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. Federal health care programs have paid hundreds of millions of dollars to reimburse ostensibly for the acquisition costs of Zemplar where such reimbursement was not warranted, and was obtained by fraud.

COUNT II

FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(G)

87. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 81 of this Complaint.

88. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

89. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay money to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased its obligation to pay money to the Government.

90. Specifically, by virtue of the Government's overpayment of reimbursement funds intended to cover the actual drug costs borne by the defendant in its purchases of Zemplar but in fact covering overfill doses of Zemplar for which the defendant did not pay and/or was otherwise separately reimbursed, defendant was obliged to refund the no-cost overfill-related reimbursements or portions of such reimbursements. Defendant made or used false records or statements material to such obligation to pay, and/or knowingly concealed or avoided such obligations despite its full awareness that it did not pay drug costs for the overfill doses it administered, in violation of 31 U.S.C. § 3729(a)(1)(G).

91. As a result of this unlawful concealment, the Government did not have returned to it reimbursement funds that should have been provided back to the Government by the defendant for costs never actually borne by the defendant.

COUNT III

FALSE CLAIMS ACT

31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B)

92. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 81 of this Complaint.

93. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

94. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, and made, used and caused to be made and used false records and statements material to false claims. Each claim for reimbursement of acquisition costs for administered doses of Epogen taken from the overfill of purchased vials which themselves were the subject of separate reimbursement claims is a false claim. The defendant did not pay any drug costs for the Epogen overfill doses, and it was not entitled to receive any additional reimbursement from Medicare or other federal health care programs for such doses. By submitting false claims seeking reimbursement for quantities of Epogen that were never purchased by it, defendant violated 31 U.S.C. § 3729(a)(1)(A) and

(a)(1)(B) and caused the federal government to pay it funds to which it was not entitled.

95. The Government, unaware of the falsity of the records, statements, and claims made or caused to be made by the defendant, has paid and continues to pay the defendant for reimbursement of purported drug costs never actually incurred by defendant and to which it is not entitled.

96. By reason of the defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. Federal health care programs have paid hundreds of millions of dollars to reimburse ostensibly for the acquisition costs of Epogen where such reimbursement was not warranted, and was obtained by fraud.

COUNT IV

FALSE CLAIMS ACT

31 U.S.C. §§ 3729(a)(1)(G)

97. Plaintiff realleges and incorporate by reference the allegations contained in paragraphs 1 through 81 of this Complaint.

98. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

99. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records or statements material to an obligation to pay money to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased its obligation to pay money to the Government.

100. Specifically, by virtue of the Government's overpayment of reimbursement funds intended to cover the actual drug costs borne by the defendant in its purchases of Epogen but in fact covering overfill doses of Epogen for which the defendant did not pay and/or was otherwise separately reimbursed, defendant was obliged to refund the no-cost overfill-related reimbursements or portions of such reimbursements. Defendant made or used false records or statements material to such obligation to pay, and/or knowingly concealed or avoided such obligations despite its full awareness that it did not pay drug costs for the purely overfill doses it administered, in violation of 31 U.S.C. § 3729(a)(1)(G).

101. As a result of this unlawful concealment, the Government did not have returned to it reimbursement funds that should have been provided back to the Government by the defendant for costs never actually borne by it.

PRAYER

WHEREFORE, plaintiff-relator prays for judgment against the defendant as follows:

A. That defendant cease and desist from violating 31 U.S.C. § 3729;

B. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of defendant's actions, plus a civil penalty of not less than $5,500 for each violation of 31 U.S.C. § 3729;

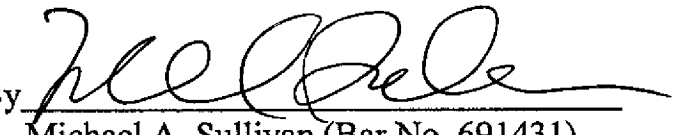
C. That the United States and plaintiff-relator be granted all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, plaintiff-relator hereby demands a trial by jury.

Dated: May 26, 2010

FINCH McCRANIE LLP

By 

Michael A. Sullivan (Bar No. 691431)
225 Peachtree St., Suite 1700
Atlanta, GA 30303
Telephone: (404) 658-9070
Facsimile: (404) 688-0649
Msullivan@finchmccranie.com

Steve W. Berman
Shayne C. Stevenson
Robert F. Lopez
HAGENS BERMAN SOBOL SHAPIRO LLP
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Daniel Kalish
LAW OFFICES OF HEYRICH KALISH MCGUIDAN PLLC
1325 Fourth Ave., Suite 540
Seattle, WA 98101
Telephone: (206) 826-5354

Attorneys for Plaintiff-Relator Chester Saldivar